

Claims

1. Stable lyophilized pharmaceutical preparation of monoclonal or polyclonal antibodies containing a sugar or an amino sugar, an amino acid and a surfactant.
2. Preparation as claimed in claim 1, wherein the preparation is essentially free of polyethylene glycols and/or free of protein-like standard pharmaceutical auxiliary substances.
3. Preparation as claimed in claim 1 or 2 composed essentially of
  - a) a monoclonal or polyclonal antibody
  - b) a sugar or amino sugar
  - c) an amino acid
  - d) an inorganic acid acting as a buffer substance and
  - e) a surfactant.
4. Preparation as claimed in one of the claims 1 -3, wherein the sugar is a monosaccharide, disaccharide or trisaccharide, preferably sucrose, maltose, trehalose or raffinose.
5. Preparation as claimed in one of the claims 1-4, wherein the amino sugar is glucosamine, N-methyl-glucosamine, galactosamine or neuraminic acid.

6. Preparation as claimed in one of the claims 1 to 5, wherein the amino acid is a basic, acidic or neutral amino acid, preferably arginine, lysine, histidine, ornithine, isoleucine, leucine, alanine, glutamic acid or aspartic acid.
7. Preparation as claimed in one of the claims 1 to 6, wherein the surfactant is a polysorbate or a polyoxyethylene-polyoxypropylene polymer.
8. Preparation as claimed in one of the claims 1 to 7, wherein it contains physiologically tolerated auxiliary substances from the group comprising acids, bases, buffers and/or isotonicizing agents.
9. Aqueous pharmaceutical preparation of monoclonal or polyclonal antibodies obtainable by redissolving the lyophilisate as claimed in one of the claims 1 to 8.
10. Aqueous pharmaceutical preparation as claimed in claim 9, wherein the solution has a pH value of 5-8, preferably of 6 - 7.4.
11. Process for the production of a lyophilized pharmaceutical preparation as claimed in one of the claims 1 to 8, wherein an aqueous preparation is produced that contains a monoclonal or polyclonal antibody as the active substance and a sugar or amino sugar, an amino acid and a surfactant as additives as well as optionally further pharmaceutical auxiliary substances and subsequently the solution is lyophilized.

09308223-081299

12. Use of a combination of auxiliary substances composed of a) a sugar or an amino sugar, b) an amino acid and c) a surfactant for the production of stable therapeutic or diagnostic agents containing antibodies.

Add a'

662F80" E2290E60